



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 29 1999

Borek Janik, Ph.D.
Official Correspondent
Morax
13805 Waterloo
Chelsea, Michigan 48118

Re: K992148
Trade Name: Hydragel ISO-CK Kit, Hydragel 7 ISO-CK Kit,
Hydragel ISO-CK 15/30 Kit, and Hydragel Mini ISO-CK Kit
Regulatory Class: II
Product Code: CGS
Dated: October 27, 1999
Received: October 29, 1999

Dear Dr. Janik:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

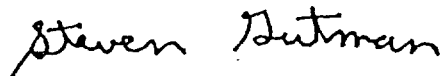
Page 2

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, flowing style.

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

K992148

Device name:

HYDRAGEL - MINI ISO-CK Kit
HYDRAGEL ISO-CK Kit
HYDRAGEL 7 ISO-CK Kit
HYDRAGEL ISO-CK 15/30 Kit

Indications For Use:

All Sebia's Hydragel ISO-CK kits are intended for the identification and quantitation of the three creatine kinase (CK) isoenzymes, MM, MB and BB, by electrophoresis on alkaline buffered agarose gels followed by a densitometry.

The creatine kinase (CK) isoenzyme, CK-MB, is primarily released from a damaged heart muscle. It is one of the earliest markers for distinguishing patients with acute myocardial infarction (AMI) from those with other coronary syndromes and episodes with similar symptoms.

Biochemical assays have been, and remain so, the most reliable means of detecting myocardial injury. However, no single biochemical marker can alone give a complete picture of myocardial injury and its extent. Therefore, the assay of CK isoenzymes is often used in tandem with the assay of LD isoenzymes, which are released slower from the injured heart muscle and remain longer in circulation, to confirm or rule out the diagnosis of MI, assess its severity and monitor patient's condition.

The principles of HYDRAGEL ISO-CK assays are: the electrophoretic separation of the CK isoenzymes, the use of a specific chromogenic substrate for the CK catalyzed visualization reaction, and densitometric quantitation of the electrophoregrams.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Coogan
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992148

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____

(Optional Format 1-2-96)